REMARKS

Applicants and their attorney would like to thank the Examiner for the courtesy of the telephonic discussions of October 29, 2003, during which the outstanding Restriction Requirement was discussed.

Claims 1-13 were pending in the application. Claims 1 and 2 have been canceled, without prejudice, and claims 3-11 have been amended. Accordingly, after the amendments presented herein have been entered, claims 3-13 will remain pending.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed.

No new matter has been added. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

RESTRICTION REQUIREMENT

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

I. Claims 1-13, drawn to anti-inflammatory compounds comprising Xa-Yn (1 to 3 amino acids)-Xaa_2 Xaa_3 Xaa_4, Xaa_5, Xaa_6-A_m (1 to 3 amino acids), wherein Xaa_1 is Leu, Ala Ile or Nor-leucine; Xaa2 is ASP, Glu, Asn, Gln, homoserine, or 2-ketopropylalanine; Xaa_3 is Trp, Phe, Tyr, 4-biphenyl-Alanine, homophenylalanine, 2-Naphthyalanine, 1-Naphthylalanine, or cycloxexyl-alanine; Xaa_4 is Ser, Ala, glu, Leu, Thr, nor-leucine, or homoserine, Xaa_5 is Trp, His, homophenylalanine; Xaa_6 is Leu, Ala, Ile, or nor-leucine, classified in class 530, subclass 300.

The Examiner is of the opinion that

[a]t least 37,632 peptides are set forth in the formula presented in claim 3. These peptides defer in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. If anyone

invention is elected, the elected invention will only be examined in-so far as it pertains to the sequences listed therein. This is not a species election. Applicants must also provide the sequence that they wish to be examined. Because the peptides are considered patentably distinct, this is NOT a species election.

Applicants hereby elect the Group I invention (claims 1-13), and the sequence RRMKWKKTALDWSWLQTE (SEQ ID NO:131), *with traverse.*

Applicants *traverse* the foregoing Restriction Requirement and request reconsideration with respect to amended claims 3-13. The peptides encompassed by claims 3-13 (i.e., defined by the core peptide structure shown in claim 3) clearly represent a single invention in that they are connected in design, operation, and effect, *i.e.*, ***are not independent*** inventions (M.P.E.P. §808.01). Specifically, the claimed anti-inflammatory peptides are designed in the same way (*i.e.*, they are designed based on the NEMO binding domain of the IKβ kinase), they operate in the same way (*i.e.*, by binding to NEMO) and they have the same effect: they inhibit the IKβ kinase activity, resulting in the inhibition of phosphorylation of IKβ and the inhibition of cytokine mediated NF-kB activation.

With respect to the Examiner's assertion that the peptides of claim 3 "differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions," Applicants respectfully note that the various substitutions set forth in claim 3 have been experimentally tested and shown by Applicants to ***retain binding to NEMO***. For example, the option in claim 3 that residue X_2 be N (glutamine) rather than D (aspartic acid) or E (glutamic acid), which the Examiner would presumably consider as a "non-conservative substitution", was shown ***not*** to effect NEMO binding (see e.g., Example 11). Indeed, as described by Applicants and demonstrated in the working examples, "it is the shape ... and not the charge of the side chain of the amino acid at this position that is critical for the interaction between IKKβ and NEMO." Therefore, the fact that certain substitutions recited in claim 3 are "non-conservative", in the sense that the charge of the side chain differs, does ***not*** render them separate and distinct inventions, since they all possess the same ***common essential design*** (i.e., "shape") that allows the peptide to bind to NEMO, a ***common essential operation***, and to inhibit inflammation, a ***common essential effect***.

Further evidence that the anti-inflammatory peptides encompassed by amended claims 1-13 do not represent separate inventions is the fact that they have all been classified in the same search Class (i.e., 530) and subclass (i.e., 300). As such, the searches with regard to these compounds would be co-extensive and would not involve a serious burden on the Examiner. The M.P.E.P. provides that a requirement for restriction must be supported by "both two-way distinctness and reasons for insisting on restriction", such as separate classification, status or field of search, separate particulars of patentability or combinations with distinct utility. M.P.E.P. § 806.05(c). In the present case, neither two-way distinctness nor reasons for insisting on restriction have been provided.

A Restriction Requirement cannot be required merely because a generic or sub-generic claim covers a large number of compounds. Such a requirement would be at odds with established U.S. Patent Office practice. This is evidenced, for example, by the issued claims in U.S. Patent Nos. 6,277,826 and 6,303,567 (copies of which are submitted herewith), which are similar in scope to claims 1-3 of the present application. Indeed, such claims are routinely issued by the U.S. Patent and Trademark Office.

For at least the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the restriction under 35 U.S.C. §121.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

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Respectfully submitted,

By _____

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